



U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Health Emergency Preparedness

Acquisition of Medical Countermeasures for Biodefense

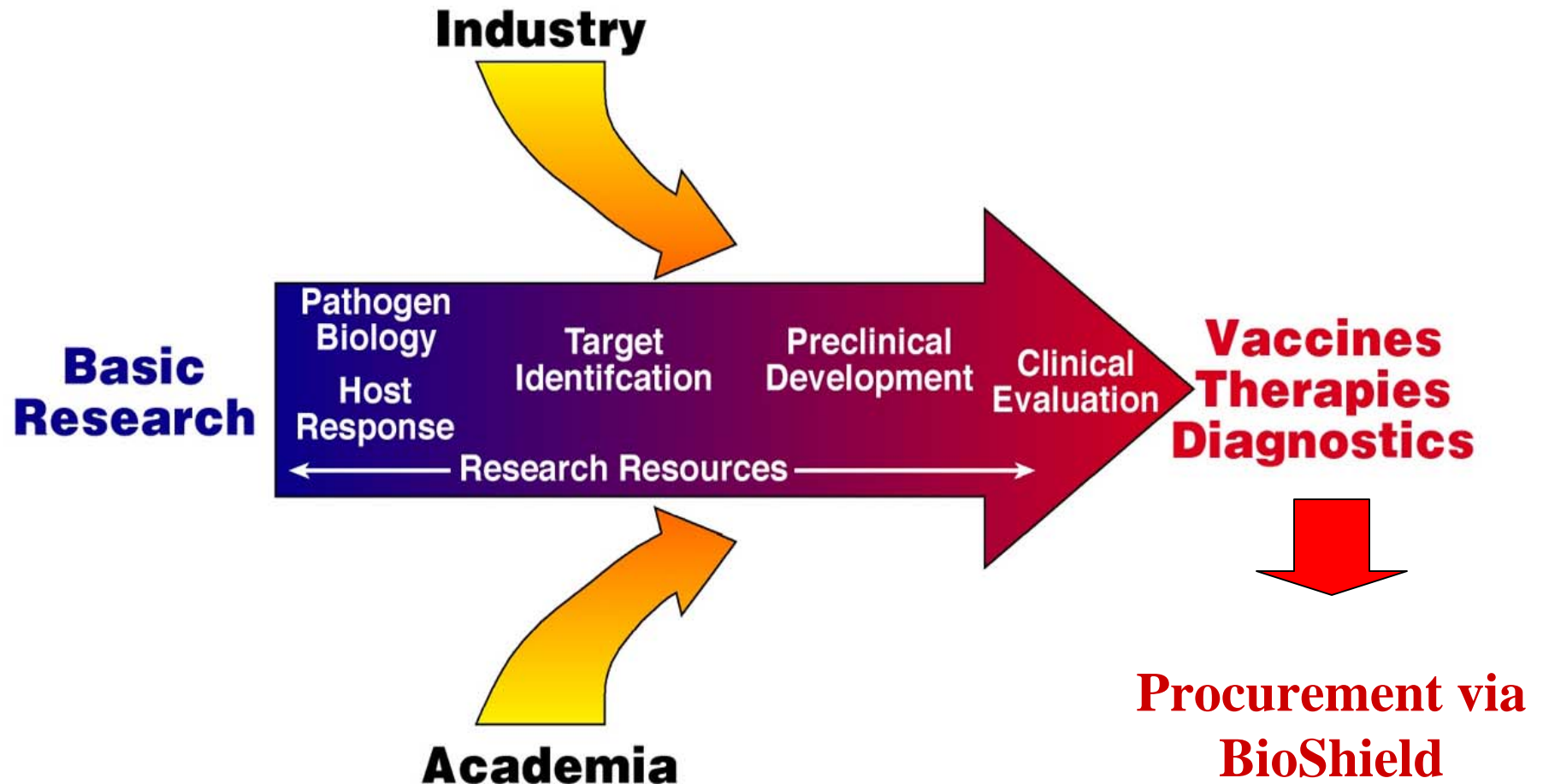
*DHHS Plans for Implementation of
Project BioShield*

Marissa A. Miller, DVM, MPH
*Strategies for Developing Therapeutics that Directly Target
Anthrax and its Toxins*
10 June 2004





Medical Countermeasures Pipeline





Project BioShield

BioShield was announced by President Bush in his State of the Union address on January 28, 2003.



Secretaries Thompson (HHS) and Ridge (DHS) jointly transmitted the "Project BioShield Act of 2003 to Congress on February 26, 2003.

Senate passed "Project BioShield Act of 2004" (S.15) on May 19, 2004 by a majority of 99-0.

Purpose: To accelerate the process of research, development, purchase, and availability of effective countermeasures against agents of bioterror.



Project BioShield

Three-pronged program:

- Establishes a secure *funding* source for purchase of critical biomedical countermeasures
- Increases NIH/NIAID *authorities* and flexibility to expedite research and development of critical biomedical countermeasures
- Establishes an FDA *Emergency Use Authorization* for critical biomedical countermeasures



Project BioShield

Establish secure funding source for purchase of critical biomedical countermeasures:

- The first ever Department of Homeland Security appropriations bill (PL 108-90) signed by President Bush on 1 October 2003 created a discretionary reserve of \$5.6 billion to fund the program through FY2013 and makes available \$890 million in discretionary funds in FY2004
- Funding would be available for countermeasures once production of licensable products is judged scientifically feasible. HHS will be the procuring authority



Release of BioShield Funds

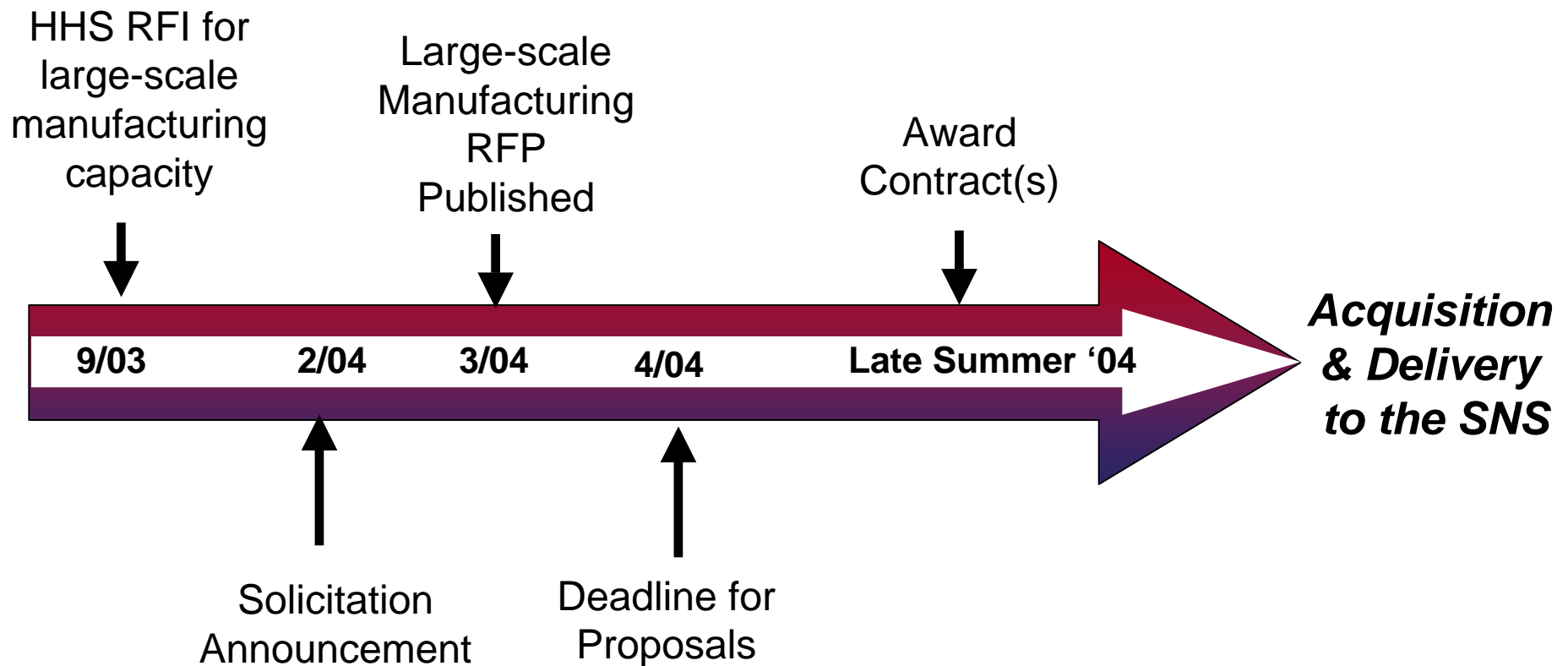
- Interagency Approval of Requirement
- Findings by Secretaries of DHS and HHS
 - ▶ Determination of material and public health threat
 - ▶ Suitability of countermeasure
 - ▶ No significant commercial market
 - ▶ Numbers of doses required and cost
- Approval by the President



White House photo by Paul Morse



Timeline for Large-scale Anthrax rPA Vaccine Acquisition





Antitoxin Treatments for Anthrax

Presolicitation Notice

- Acquisition of commercial products or products in advanced development for the treatment of inhalational anthrax disease
- Including but not limited to:
 - ▶ Monoclonal anti-PA antibodies, polyclonal anti-anthrax antibodies and human immunoglobulin
 - ▶ Therapeutic proteins, and small molecular entities
- Notice #2004-N-01385:
 - ▶ Posted: June 9, 2004
 - ▶ POC: Vivian Hubbs, (770) 488-2647, vdh6@cdc.gov
Lorenzo Falgiano, (770) 2629, ljf5@cdc.gov
 - ▶ <http://www2.ehs.gov/spg/HHS/CDTCP/PGOA/2004%2DN%2D01385/SynopsisP.html>